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Dated: January 30, 1998.

Janice F. Oliver,

Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–3357 Filed 2–10–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 97N–0301]

Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations for Nylon 6/66 resins to change the melting point range from 380–400 °F to 380–425 °F. This action is in response to a petition filed by Ube Industries (America), Inc.

DATES: Effective February 11, 1998; written objections and requests for a hearing by March 13, 1998.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 21, 1997 (62 FR 39003), FDA announced that a food additive petition (FAP 7B4548) had been filed by Ube Industries (America), Inc., c/o Center for Regulatory Services, 2347 Paddock Lane, Reston, VA 20191. The petition proposed to amend the food additive regulations in § 177.1500 *Nylon resins* (21 CFR 177.1500), for Nylon 6/66 resins described in the table in paragraph (b), entry 4.2, to change the melting point range from 380–400 °F to 380–425 °F.

The filing notice for the petition (62 FR 39003) stated that the action resulting from the petition qualified for a categorical exclusion under previous 21 CFR 25.24(9). This was a misprint and should have cited 21 CFR 25.24(a)(9). Upon further review, the agency determined that such a categorical exclusion, which is based on a technical change in a regulation, is not appropriate for this proposed action because the proposed amendment is not simply a technical change. Consequently, the agency considered the environmental effects of this action.

FDA has evaluated data in the petition supporting the chemical identity of the additive and other relevant material. The agency finds that the petitioner has adequately demonstrated that Nylon 6/66 with a melting point that includes the range from 400–425 °F meets the specifications under § 177.1500(b), entry 4.2. Based on this information the agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and that therefore, (3) the regulations in § 177.1500 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before March 13, 1998, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 177

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

§ 177.1500 [Amended]

2. Section 177.1500 *Nylon resins* is amended in the table in paragraph (b) for entry ''4.2'' under the heading ''Melting point (degrees Fahrenheit)'' by removing ''380–400'' and adding in its place ''380–425''.

Dated: January 30, 1998.

Janice F. Oliver,

Acting Director, Center for Food Safety and Applied Nutrition.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 312 and 314

[Docket No. 95N–0010]

Investigational New Drug Applications and New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations pertaining to new drug applications (NDA's) to clearly define in the NDA format and content regulations the requirement to present effectiveness and safety data for important demographic subgroups, specifically gender, age, and racial subgroups. FDA